Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

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Report Date:04/29/2009

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|--|-------------------------------------|----------------------------------|----------------------------------|---|--|--|--|
| | | | | Ma | ale | | |
| Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory | 058812305 052000505 059501107 | 03/21/01 01/21/04 03/06/02 | 727 727 727 | 50 (3) 50 (3) 50 (3) | 26(673) 30(679) 22(673) | 509.7 498.5 510.3 | Formamide Ginseng 5-(Hydroxymethyl)-2-furfural |
| | | | | Fen | nale | | |
| Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory | 058812305 052000505 059501107 | 03/20/01 01/22/04 03/07/02 | 730 728 728 | 50 (5) 50 (5) 50 (5) | 38(703) 36(700) 31(679) | 358.3 355.0 332.2 | Formamide Ginseng 5-(Hydroxymethyl)-2-furfural |

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 99

| | | | Male | | Female |
|--|-------|--------------------------------|---|-------------------------------|---|
| #All Organs: Benign Tumors | | | | | |
| _ | | 45/50 (90%) | 49/50 (98%) 50/50 (100 | 9%) 43/50 (86%) | 42/50 (84%) 46/50 (92%) |
| verall Incidence | Total | 144/150 (96%) | Mean 96% SD 5.29% | Total 131/150 (87.33) | %) Mean 87.33% SD 4.16% |
| All Organs: Malignant Tumors | | | | | 40/50 (200/) 46/50 (200/) |
| verall Incidence | Total | 25/50 (50%) 86/150 (57.33%) | 26/50 (52%) 35/50 (70% Mean 57.33% SD 11.02% | , | , |
| All Organs: Malignant and Benign Tu | | 48/50 (96%) | 49/50 (98%) 50/50 (100 | | 45/50 (90%) 48/50 (96%) |
| verall Incidence | Total | 147/150 (98%) | Mean 98% SD 2% | Total 142/150 (94.67) | , , |
| All Organs: Hemangioma | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) | Mean 0% SD 0% |
| All Organs: Hemangiosarcoma | | 2/22 (224) | | | |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| All Organs: Hemangiosarcoma or He | | | | | 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | , | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) | iviean 0% SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 100

Report Date: 04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #All Organs: **Histiocytic Sarcoma** 1/50 (2%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Leukemia: Erythrocytic 0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 15/50 (30%) 18/50 (36%)28/50 (56%) (20%) (12%)(18%)SD 13.61% SD 4.16% Overall Incidence Total 61/150 (40.67%) Mean 40.67% Total 25/150 (16.67%) Mean 16.67% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total SD 0% Total 0/150 (0%) Mean 0% 0/150 (0%) Mean 0% #All Organs: Mesothelioma: Benign, Malignant, NOS (4%)(0%)(0%)2/50 (4%)0/50 **Overall Incidence** 6/150 (4%) SD 0% 2/150 (1.33%) SD 2.31% Total Mean 4% Total Mean 1.33%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 101

Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

| | | | Male | | | | Female | |
|---|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #All Organs: Mesothelioma: Malignant | | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 6/150 (4%) | Mean 4% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| #All Organs: Osteoma | | 0/50 (00) | 0/50 (001) | 0/50 (004) | | 0/50 (00) | 2/52 /22/ | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #All Organs: Osteosarcoma | ••••• | 0/50 /00() | 4/50 (00/) | 0/50 (0%) | | 0/50 (00/) | 0/50 /0%) | 4/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| #All Organs: Osteosarcoma or Osteoma | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| *Adrenal Cortex: Adenoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| *Adrenal Cortex: Carcinoma | ••••• | 4/50 /00() | 0/50 (0%) | 0/50 (0%) | | 0/50 (00/) | 0/50 /0%) | 0/50 /00/ |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Vehicle: WATER

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 102

Species: RATS

Imor Incidence for Selected Control An Route: GAVAGE Report Date:04/29/2009

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|----------|----------------------------|-----------------------|------------------------|-------|----------------------------|-------------------------|-----------------------|
| Adrenal Medulla: Ganglioneuroma | | | | | | | | |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Adrenal Medulla: Hemangioma | | 0/50 (00/) | 0/50 (00/) | 0/50 (00) | | 0/50 (00) | 0/50 (00/) | 0/50 (00/) |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Adrenal Medulla: Pheochromocytoma Benign | | -/ | | | | - 4 | | |
| overall Incidence | Total | 9/50 (18%) 18/150 (12%) | 4/50 (8%) Mean 12% | 5/50 (10%) SD 5.29% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| drenal Medulla: Pheochromocytoma Comple | x | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| drenal Medulla: Pheochromocytoma Maligna | ınt | | | | | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Adrenal Medulla: Pheochromocytoma: Benign | , Comple | | 4/50 (00/) | 5/50 (400) | | 0/50 (00) | 4/50 (00) | 0/50 (00) |
| overall Incidence | Total | 9/50 (18%) 18/150 (12%) | 4/50 (8%) Mean 12% | 5/50 (10%) SD 5.29% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 103

| | | | Male | | | | Female | |
|-----------------------------------|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Bone: Chondrosarcoma | | | 2/22 (221) | 2/22 (22) | | 2/52 (22) | 2(7-2) | 2/72 (221) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Bone: Chondrosarcoma or Chond | Iroma | 0/50 /00/ | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (0%) | 0/50 /00/ |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Bone: Chordoma | | 4/50 (00() | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (0%) | 0/50 (00/) |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Bone: Osteoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Bone: Osteosarcoma | | 0/50 (/0//) | 4/50 (20/) | 0/50 (09/) | | 0/50 (00/) | 0/50 (0%) | 4/50 (20() |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| #Bone: Osteosarcoma or Osteoma | | | (00) | | | (201) | 0/20 (00) | (00) |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 104 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-------------------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| *Brain: Astrocytoma Malignant Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Brain: Ependymoma Benign | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Brain: Ependymoma Malignant Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Brain: Glioma Malignant Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Brain: Granular Cell Tumor Benig Overall Incidence | n Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| *Brain: Medulloblastoma Mal | | 0/50 (09/) | 0/50 (0%) | 0/50 (00/) | | 0/50 (00/) | 0/50 (09/) | 0/50 (09/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

| | | | Male | | | | Female | |
|------------------------------------|--------------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| Brain: Meningioma Malignant | | 0/50 (00/) | 0/50 (00) | 0/50 (00/) | | 0(50 (00)) | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Brain: Meningioma: Benign, Mali | gnant, NOS | 0/50 (00/) | 0/50 (00/) | 0/50 (09/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (09/) |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Brain: Oligodendroglioma Benigi | 1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Brain: Oligodendroglioma Malign | ant | 2/20 (201) | | | | (201) | (201) | 0.50 |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Brain: Oligodendroglioma, Gliom | a, or Astroc | | | | | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Brain: Osteosarcoma | | 0/50 (00/) | 0/50 (00) | 0/50 (0%) | | 0/50 (00/) | 0/50 (00/) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 106

Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

| | | | Male | | | | Female | |
|--|-------|----------------------------|-------------------------|------------------------|-------|----------------------------|-------------------------|-----------------------|
| *Brain: Schwannoma Malignant | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Clitoral/Preputial Gland: Adenoma | | (20) | 2/22 (22) | 7/70 (1001) | | 2/22 (101) | (00) | (90) |
| Overall Incidence | Total | 1/50 (2%) 6/150 (4%) | 0/50 (0%) Mean 4% | 5/50 (10%) SD 5.29% | Total | 2/50 (4%) 6/150 (4%) | 1/50 (2%) Mean 4% | 3/50 (6%) SD 2% |
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | 2/50 (4%) | 0/50 (0%) | 6/50 (12%) | | 2/50 (4%) | 2/50 (4%) | 3/50 (6%) |
| Overall Incidence | Total | 8/150 (5.33%) | Mean 5.33% | SD 6.11% | Total | 7/150 (4.67%) | Mean 4.67% | SD 1.15% |
| *Clitoral/Preputial Gland: Fibrosarcoma | | 0/50 (0%) | 0/50 (00() | 0/50 (0%) | | 0/50 (00/) | 0/50 (0%) | 0/50 /09/ |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Clitoral/Preputial Gland: Sarcoma | | | | 0/50 (00) | | | | (201) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

| | | | Male | | | | Female | |
|--|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| Clitoral/Preputial Gland: Squamous Cell Papilloma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Ear: Neural Crest Tumor | •••• | 0/50 (00/) | 0/50 (00() | 0/50 (00/) | | 0/50 (00) | 0/50 (0%) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Esophagus: Fibrosarcoma | •••• | 0/50 (00/) | 0/50 (00%) | 0/50 (00/) | | 0/50 (00) | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Esophagus: Lipoma | | 0/50 (00/) | 0/50 (00() | 0/50 (00/) | | | 0/50 (00/) | 0/50 (004) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Eye: Amelanotic Melanoma, Ben | ign | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Eye: Melanoma Malignant | | 0/50 (00/) | 0/50 (00() | 0/50 (00/) | | 0/50 (00) | 4/50 (00/) | 0/50 /00/ |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 108

| | | | Male | Female |
|--|-------|----------------------------|--|---|
| Eye: Schwannoma Malignant | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% |
| Harderian Gland: Carcinoma | | | | 0/50 (00) 0/50 (00) 0/50 (00) |
| verall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% |
| larderian Gland: Carcinoma or Adenoma | | | | |
| verall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15% | 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% |
| eart: Schwannoma Benign | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% SD 0% | Total 0/150 (0%) Mean 0% SD 0% |
| eart: Schwannoma Malignant | | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |
| ntestine Large: Colon/Rectun Adenoma | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 109

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Intestine Large: Colon/Rectur Carcinoma | n: | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Large: Colon/Rectur Carcinoma or Adenoma | n: | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Intestine Large: Colon/Rectur Hemangioma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/30 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Duodenum: Carcinoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Duodenum: Leiomyoma | | - / | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| #Intestine Small: Jejunum: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 110

| | | | Male | | | | Female | |
|---|---------|---------------|------------|------------|-------|------------|-----------|------------|
| Intestine Small: Jejunum: Granular Cell Tumor Mali | ignant | | | | | | | |
| Grandial Con Famol Man | gnan | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ntestine Small: Jejunum: Leiomyoma | | | | | ••••• | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ntestine Small: Jejunum: Leiomyosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ntestine Small: Site Unspec Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ntestine Small: Site Unspec Carcinoma or Adenoma | cified: | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ntestine Small: Site Unspec Granular Cell Tumor Mali | | 0(50 (00)) | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 /00/ | 0/50 (00/) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 111

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|---------------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Intestine Small: Site Unspecif Leiomyoma | fied: | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Intestine Small: Site Unspecif Leiomyosarcoma | fied: | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Islets, Pancreatic: Adenoma | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 4/150 (2.67%) | Mean 2.67% | SD 2.31% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |
| *Islets, Pancreatic: Carcinoma | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 2% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Islets, Pancreatic: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 3/50 (6%) 7/150 (4.67%) | 0/50 (0%) Mean 4.67% | 4/50 (8%) SD 4.16% | Total | 1/50 (2%) 2/150 (1.33%) | 1/50 (2%) Mean 1.33% | 0/50 (0%) SD 1.15% |
| *Kidney: Pelvis and Transition Carcinoma | al Epitheliui | m: | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 112

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|---------------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| *Kidney: Pelvis and Transition Carcinoma or Adenoma | al Epitheliur | n: | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Kidney: Pelvis and Transition Papilloma | al Epitheliur | | 0/50 (00/) | 0/50 (00/) | | 0(50 (00)) | 0/50 (00) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | | |
| *Kidney: Renal Tubule: Adenoma | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 2% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | |
| 3 | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 113

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | Female |
|--|-------|-------------------------|---------------------------------|--------------------------------------|--------------------------------------|
| *Kidney: Renal Tubule: Lipoma | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 Mean 0% SD 09 | (0%) 0/50 (0%) % Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| | | | | | |
| *Kidney: Renal Tubule: Mesenchymal Tumor Benign | | 0/50 (0%) | 0/50 (0%) 0/50 | (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 09 | ` ' | Mean 0% SD 0% |
| *Kidney: Renal Tubule: Nephroblastoma | ••••• | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 Mean 0% SD 09 | (0%) 0/50 (0%) % Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| *Kidney: Renal Tubule: Sarcoma | | 2/22 (221) | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 Mean 0% SD 09 | (0%) 0/50 (0%) % Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| *Liver: Cholangioma | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 Mean 0% SD 09 | (0%) 0/50 (0%) % Total 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% |
| *Liver: Hemangiosarcoma | | ••••• | | | |
| • | Tatal | 0/50 (0%) | ` , | (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% SD 09 | % Total 0/150 (0%) | Mean 0% SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 114

| | | | Male | | | | Female | |
|---|-----------------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| Liver: Hepatocellular Adenor | ma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| iver: Hepatocellular Carcino | oma | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| iver: Hepatocellular Carcino | oma or Hepatob | lastoma | | | | | | |
| | - | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| iver: Hepatocellular Carcino | oma or Hepatoc | | 4/50 (20/) | 0/50 (00/) | | 2/50 (40/) | 0/50 (00/) | 0/50 /00/ |
| verall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 2/50 (4%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 0/50 (0%) SD 2.31% |
| | | 1/130 (0.07 /8) | | | | , , | | 3D 2.31/6 |
| iver: Hepatocellular Carcino Hepatoblastoma | oma, Hepatocell | • | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| ung: Alveolar/Bronchiolar A | Adenoma | 0/50 (/0//) | 0/50 (00/) | 0/50 (09/) | | 4/50 (20/) | 1/50 (29/) | 0/50 /09/ \ |
| | Takel | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Tatal | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 115

| | | | Male | | | | Female | |
|---|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| Lung: Alveolar/Bronchiolar Carcin | oma | 4/50 (20/) | 0/50 (00() | 1/50 (20/) | | 4/50 /20/ | 0/50 (09/) | 0/50 (09/) |
| Overall Incidence | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| Lung: Alveolar/Bronchiolar Carcin Adenoma | | | | | | | | |
| overall Incidence | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | Total | 2/50 (4%) 3/150 (2%) | 1/50 (2%) Mean 2% | 0/50 (0%) SD 2% |
| ung: Fibrosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ung: Hemangiosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| ung: Sarcoma | | 0/50 (09/) | 0/50 (0%) | 0/50 (0%) | | 0/50 (00/) | 0/50 (09/) | 0/50 (0%) |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| ung: Squamous Cell Carcinoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 116 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | · | | Male | | | | Female | |
|---|--------|----------------------------|-------------------------|-----------------------|--------|----------------------------|-------------------------|-----------------------|
| #Lymph Node: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | wican 070 | | | | ivican 070 | |
| #Mammary Gland: Adenolipoma | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | 0/50 (00) | 0/50 /00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Overall moldenee | | , , | | | | , | | |
| #Mammary Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 4/150 (2.67%) | 2/50 (4%) Mean 2.67% | 2/50 (4%) SD 2.31% |
| Overall illicidence | I Olai | 1/130 (0.07/8) | IVIEAIT 0.07 /6 | 30 1.13% | I Olai | 4/130 (2.07/6) | ivieaii 2.07 /6 | 3D 2.31/0 |
| #Mammary Gland: Carcinoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | 0/50 (0%) SD 2.31% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) SD 1.15% | Total | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) SD 0% |
| Overali incidence | Total | 1/150 (0.67%) | Mean 0.67% | 1.15% | Total | 6/150 (4%) | Mean 4% | 3D 0% |
| #Mammary Gland: Fibroadenoma | | | | | | | | |
| Occupation of the second | T-1-1 | 2/50 (4%) | 2/50 (4%) | 1/50 (2%) | T-1-1 | 33/50 (66%) | 32/50 (64%) | 29/50 (58%) |
| Overall Incidence | Total | 5/150 (3.33%) | Mean 3.33% | SD 1.15% | Total | 94/150 (62.67%) | Mean 62.67% | SD 4.16% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 117

| | | | Male | | | | Female | |
|---|-----------------|----------------------------|-------------------------|-----------------------|-------|-----------------------------|-------------------------|-------------------------|
| Mammary Gland: Fibroma | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| Mammary Gland: Fibroma, Fibroadenoma | a or Adenoma | | | | | | | |
| overall Incidence | Total | 4/50 (8%) 7/150 (4.67%) | 2/50 (4%) Mean 4.67% | 1/50 (2%) SD 3.06% | Total | 33/50 (66%) 96/150 (64%) | 33/50 (66%) Mean 64% | 30/50 (60%) SD 3.46% |
| Mammary Gland: Fibroma, Fibroadenoma | a, Carcinoma, c | or Adenoma 4/50 (8%) | 2/50 (4%) | 1/50 (2%) | | 35/50 (70%) | 33/50 (66%) | 30/50 (60%) |
| overall Incidence | Total | 7/150 (4.67%) | Mean 4.67% | SD 3.06% | Total | 98/150 (65.33%) | Mean 65.33% | SD 5.03% |
| Mesentery: Fibrosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Mesentery: Hemangiosarcoma | | | (00) | | | 0/20 (004) | (00) | . (201) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Mesentery: Lipoma | | 0/50 (00/) | 0/50 /0% | 0/50 (00/) | | 0/50 (00/) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 118

| | | | Male | | | | Female | |
|---|---------------|----------------------|------------|------------|-------|---------------|------------|--------------------|
| Mesentery: | | | | | | | | |
| Rhabdomyosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Nose: Adenoma | | 0.50 | -(| | | -() | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Nose: | | | | | | | | |
| Chondroma | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Nose: | | | | | | | | |
| Squamous Cell Carcinom | а | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (0%) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | () | 0/50 (0%) SD 0% |
| | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Oral Cavity (Oral Mucosa, To Papilloma Squamous or F | ongue, Phary | | | | | | | |
| i apilionia oqualilous oi i | аршоша | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | ` , | | | | | | |
| Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom | | nx, Tooth, Gingiva): | | | | | | |
| - 4 | · | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data M

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 119

| | | | Male | | | | Female | | | | |
|---|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|--|--|--|
| Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma, I Papilloma | | | | | | | | | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | | | |
| Oral Mucosa: Squamous Cell Carcinoma | | | | | | (201) | (00) | (201) | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | | | |
| oral Mucosa: Squamous Cell Papilloma | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | |
| verall Incidence | Total | 0/30 (0%) | Mean 0% | SD 0% | Total | 0/30 (0%) | Mean 0% | SD 0% | | | |
| vary: Cystadenoma | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | | |
| verall Incidence | | | | | Total | 0/149 (0%) | Mean 0% | SD 0% | | | |
| vary: Granulosa Cell Tumor Benig | n | | | | | 0/50 (00/) | 0/50 (00/) | 0/40 (00/) | | | |
| verall Incidence | | | | | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% | | | |
| ovary: Granulosa Cell Tumor Maligi | nant | | | | | 0/50 (09/) | 0/50 (09/) | 0/40 (09/) | | | |
| verall Incidence | | | | | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 120

Report Date:04/29/2009

Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|----------------------------------|----------------|----------------------------|-------------------------|-----------------------|-------|-------------------------|----------------------|--------------------|
| *Ovary: Granulosa Cell Tumor: | Benign, Malign | ant, NOS | | | | 0/50 (0%) | 0/50 (0%) | 0/40 (0%) |
| Overall Incidence | | | | | Total | 0/50 (0%) 0/149 (0%) | Mean 0% | 0/49 (0%) SD 0% |
| *Ovary: Granulosa-Theca Tumo | r Benign | | | | | | | 0/40 /00/\ |
| Overall Incidence | | | | | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% |
| *Ovary: Granulosa-Theca Tumo | r Malignant | | | | | 0/50 (00/) | 0/50 (00/) | 0/40 /00/\ |
| Overall Incidence | | | | | Total | 0/50 (0%) 0/149 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% |
| *Ovary: Tubulostromal Adenom | na | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | | | | | Total | 0/149 (0%) | Mean 0% | SD 0% |
| *Pancreas: Adenoma | | 0/50 (00/) | 0/50 (00/) | 4/50 (001) | | 0(50 (00)) | 0/50 (00) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| *Pancreas: Carcinoma | | 0/50 /00() | 0/50 (00/) | 0/50 (00/) | | 0/50 (0%) | 0/50 /00/ | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

| | | | Male | | | | Female | |
|---|-------------|----------------------------|-------------------------|-----------------------|-------|-------------------------|----------------------|--------------------|
| Pancreas: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Pancreas: Mixed Tumor Benign | | 0/50 (00/) | 0/50 (00/) | 0/50 (09/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00() |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Pancreas: Mixed Tumor Malignant | | 0/50 (00() | 0/50 (00() | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00() |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Parathyroid Gland: Adenoma | | | | | ••••• | | | |
| overall Incidence | Total | 0/48 (0%) 0/147 (0%) | 0/50 (0%) Mean 0% | 0/49 (0%) SD 0% | Total | 0/46 (0%) 0/142 (0%) | 0/48 (0%) Mean 0% | 0/48 (0%) SD 0% |
| Peripheral Nerve: Schwannoma Malignant | | 0/50 (00() | 0/50 (00() | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Peripheral Nerve: Schwannoma: Benign, Mali | ignant, NOS | | 0/50 (004) | 0/50 (00/) | ••••• | 0/50 (00) | 0/50 (00) | 0/50 (00/) |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Page: 122

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-----------------|-----------------|-------------|-------------|-------|-----------------|-------------|-------------|
| Pituitary Gland: Pars Dista Adenoma | lis or Unspecif | ied Site: | | | | | | |
| | | 11/50 (22%) | 20/50 (40%) | 15/50 (30%) | | 22/50 (44%) | 16/50 (32%) | 24/50 (48%) |
| verall Incidence | Total | 46/150 (30.67%) | Mean 30.67% | SD 9.02% | Total | 62/150 (41.33%) | Mean 41.33% | SD 8.33% |
| rituitary Gland: Pars Dista Carcinoma | lis or Unspecif | ied Site: | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 3/150 (2%) | Mean 2% | SD 2% |
| Pituitary Gland: Pars Dista Carcinoma or Adenoma | lis or Unspecif | | | | | | ••••• | |
| | | 11/50 (22%) | 20/50 (40%) | 15/50 (30%) | | 24/50 (48%) | 16/50 (32%) | 25/50 (50%) |
| verall Incidence | Total | 46/150 (30.67%) | Mean 30.67% | SD 9.02% | Total | 65/150 (43.33%) | Mean 43.33% | SD 9.87% |
| Pituitary Gland: Pars Dista | lis or Unspecif | ied Site: | | | | | | |
| Ganglioneuroma | • | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Pituitary Gland: Pars Interr Adenoma | nedia: | | | | | | ••••• | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| rituitary Gland: Pars Interr Carcinoma | nedia: | | | | | | ••••• | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 123

| | | | Male | | | | Female | | |
|---|----------|---------------|------------|-----------------------|----------|------------|------------|-----------|--|
| *Pituitary Gland: Pars Intermed Carcinoma or Adenoma | dia: | | | | | | | | |
| Carcinoma or Adenoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| *Prostate: Adenoma | | | | | ••••• | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | | | | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | | | | | |
| *Prostate: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | | | | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | | | | | |
| *Salivary Glands: Sarcoma | | | | | ••••• | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | - | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| #Seminal Vesicle: Adenoma | | 2(-2) | (201) | - ((((((((((| | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | | | | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | | | | | |
| #Skeletal Muscle: Fibrous Histiocytoma | | 0/50 /00/ | 0/50 /00/ | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (0%) | |
| | . | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | - | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female **#Skeletal Muscle:** Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% **#Skeletal Muscle:** Lipoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0% **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 0%

Page: 124

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

| | | | Male | | | | Female | |
|--|---------------|-------------------------|----------------------|--------------------|----------|----------------------------|-------------------------|-----------------------|
| Skin: Basal Cell Adenoma | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% |
| Skin: | | | | | | | | |
| Basal Cell Adenoma or | Basosquamou | s Tumor Benign | 4/50 (00/) | 4/50 (00/) | | 4/50 (00/) | 4/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 1/50 (2%) 3/150 (2%) | 1/50 (2%) Mean 2% | 1/50 (2%) SD 0% | Total | 1/50 (2%) 2/150 (1.33%) | 1/50 (2%) Mean 1.33% | 0/50 (0%) SD 1.15% |
| Skin: Basal Cell Adenoma, B Trichoepithelioma | | | 1/50 (2%) | 1/50 (2%) | | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) |
| verall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 3/150 (2%) | Mean 2% | SD 2% |
| Skin: Basal Cell Carcinoma | ••••• | 2/22 (201) | | | ••••• | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Skin: | | | | | | | | |
| Basal Cell Carcinoma o | or Basosquamo | us Tumor (malignant o | r | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Skin: Basal Cell Carcinoma, Tumor (benign, malign: | | Trichoepithelioma | | | | | | |
| | - | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | T | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 3/150 (2%) | Mean 2% | SD 2% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 126

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | | | |
|--|---|-------------------------------|--------------------------|------------------------|-------|----------------------------|-------------------------|-----------------------|--|--|
| #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 10/50 (20%) 2/50 (4%) 4/50 (8%) 4/50 (8%) 3/50 (6%) 0/50 (0%) | | | | | | | | | | |
| Overall Incidence | Total | 16/150 (10.67%) | 2/50 (4%) Mean 10.67% | 4/50 (8%) SD 8.33% | Total | 7/150 (4.67%) | Mean 4.67% | 0/50 (0%) SD 4.16% | | |
| #Skin: Fibroma | | | | | | | | | | |
| Overall Incidence | Total | 6/50 (12%) 13/150 (8.67%) | 2/50 (4%) Mean 8.67% | 5/50 (10%) SD 4.16% | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | | |
| Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma | | | | | | | | | | |
| Overall Incidence | Total | 7/50 (14%) 16/150 (10.67%) | 3/50 (6%) Mean 10.67% | 6/50 (12%) SD 4.16% | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | | |
| Skin: Fibrosarcoma | ••••• | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% | | |
| Skin: Fibrosarcoma, Sarcoma, Histiocytoma | | , | | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 3/150 (2%) | 1/50 (2%) Mean 2% | 1/50 (2%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | | |
| Skin: Fibrous Histiocytoma | • | | | | ••••• | | | | | |
| Overall Incidence | Total | 1/50 (2%) 2/150 (1.33%) | 1/50 (2%) Mean 1.33% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Page: 127 Report Date:04/29/2009

Species: RATS Strain: F344

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|------------------------------|-------|------------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| #Skin: Hemangioma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Skin: Hemangiosarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Skin: Keratoacanthoma | ••••• | 8/50 (16%) | 0/50 (0%) | 2/50 (4%) | ••••• | 2/50 (4%) | 2/50 //49/) | 0/50 (09/) |
| Overall Incidence | Total | 8/50 (16%) 10/150 (6.67%) | 0/50 (0%) Mean 6.67% | 2/50 (4%) SD 8.33% | Total | 2/50 (4%) 4/150 (2.67%) | 2/50 (4%) Mean 2.67% | 0/50 (0%) SD 2.31% |
| #Skin: Lipoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/30 (0%) | Mean 0% | SD 0% | Total | 0/30 (0%) | Mean 0% | SD 0% |
| #Skin: Liposarcoma | | 0/50 (00() | 0/50 (00/) | 0/50 /00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (0)() |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Skin: Neural Crest Tumor | | 0/50 (00/) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (/0//) | 0/50 (0%) | 0/50 (09/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 128

| | | | Male | | | | Female | |
|---|--------------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| Skin: Neural Crest Tumor, Maliç | gnant | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | 0,100 (070) | | | | ` ' | | |
| Skin: Neurofibroma or Schwani | noma benign | | | | | | | |
| overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Skin: Neurofibrosarcoma or Sc | hwannoma (r | malignant or NOS) | | | ••••• | | | |
| Neuronbrosarooma or oo | nwamoma (i | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| verall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Skin: Neurofibrosarcoma, Neur malignant or NOS) | ofibroma, or | Schwannoma (benign, | | | | | | |
| manghant of itoo, | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| verall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Skin: Sarcoma | | | | | | | | |
| Normall In all Innas | T-1-1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | T-1-1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Skin: Schwannoma Benign | | (201) | | | | | 2(-2) | 2/22 (221) |
| Wordl Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) SD 0% | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/150 (0%) | Mean 0% | 3D 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 129

| | | | Male | | | | Female | |
|---|--|---------------------------------|---------------------------------------|-----------------------------------|----------------|--|---------------------------------------|-----------------------|
| ≮Skin: Schwannoma Malignant | : | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 1/50 (2%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| | | | | | | ` ' | | |
| Skin: Squamous Cell Carcino | ma | | | | | | | |
| N | T-1-1 | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | T-1-1 | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Skin: Squamous Cell Carcino Basosquamous Tumor (| | | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| Skin: Squamous Cell Papillon | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| | Total | ` , | 0/00 (0/0) | 0/00 (0/0) | | ` ' | ` ' | ` ' |
| verali incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| Overall Incidence fSkin: Squamous Cell Papillon | | a | | | Total | | | |
| Skin: Squamous Cell Papillon | | | Mean 0.67% 0/50 (0%) Mean 0.67% | SD 1.15% 0/50 (0%) SD 1.15% | Total Total | 1/150 (0.67%) 0/50 (0%) 1/150 (0.67%) | Mean 0.67% 1/50 (2%) Mean 0.67% | O/50 (0%) SD 1.15% |
| Skin: Squamous Cell Papillon Overall Incidence | na or Papilloma Total na, Papilloma, | a 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|------------|----------------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| #Skin: Squamous Cell Papilloma, | Papilloma, | or Keratoacanthoma 9/50 (18%) | 0/50 (0%) | 2/50 (4%) | | 2/50 (4%) | 3/50 (6%) | 0/50 (0%) |
| Overall Incidence | Total | 11/150 (7.33%) | Mean 7.33% | SD 9.45% | Total | 5/150 (3.33%) | Mean 3.33% | SD 3.06% |
| #Skin: Trichoepithelioma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Skin: Sebaceous Gland: Adenoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Skin: Sebaceous Gland: Carcinoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Skin: Sebaceous Gland: Carcinoma or Adenoma | | 0/50 (09/) | 0/50 (00/) | 0/50 (00/) | ••••• | 0/50 (00/) | 0/50 (0%) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Spinal Cord: Astrocytoma Benign | | | | | ••••• | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

| | | | Male | | | | Female | |
|---------------------------------------|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|-----------------------|
| Spinal Cord: Astrocytoma Malignant | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | 0/50 /00/ | 0/50 (00/) | 0/50 (00/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Spinal Cord: Glioma Malignant | •••• | 0.70 | 2/22 (221) | 0.770 (00.0) | | (201) | (00) | 2/22 (224) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| Spleen: Fibrosarcoma | | | | | | | | |
| verall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| pleen: Fibrous Histiocytoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| verall Incidence | Total | 0/30 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| pleen: Hemangioma | ••••• | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Spleen: Hemangiosarcoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---|-------------|-------------------------|----------------------|--------------------|-------|-------------------------|-------------------------|-----------------------|
| *Spleen: Leiomyosarcoma | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/30 (0%) | Mean 0% | SD 0% |
| *Spleen: Sarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Stomach, Forestomach: Leiomyosarcoma | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/) | | 0/50 /00/ | 0/50 (00/) | 0/50 (00()) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Stomach, Forestomach: Squamous Cell Carcinoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| #Stomach, Forestomach: Squamous Cell Carcinoma | or Papillom | | 0/50 (0%) | 0/50 (0%) | ••••• | 0/50 (0%) | 0/50 (0%) | 4/50 (20/) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 1/50 (2%) SD 1.15% |
| #Stomach, Forestomach: Squamous Cell Papilloma | | | | | | ••••• | ••••• | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|---------------------------------|-------|-------------------------|----------------------|--------------------|-------|----------------------------|-------------------------|----------------------|
| #Stomach, Glandular: Lipoma | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | | |
| #Stomach, Glandular: Sarcoma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| *Testes: Adenoma | | 44/50 (88%) | 45/50 (90%) | 48/50 (96%) | | | | |
| Overall Incidence | Total | 137/150 (91.33%) | Mean 91.33% | SD 4.16% | | | | |
| *Thymus: Sarcoma | | 0/49 (0%) | 0/50 (0%) | 0/48 (0%) | | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 0/144 (0%) | Mean 0% | SD 0% |
| *Thymus: Thymoma Benign | | 0/40 /00/ | 0/50 (0%) | 0/49 (09/) | | 0/49 (00/) | 0/49 (09/) | 4/40 (20%) |
| Overall Incidence | Total | 0/49 (0%) 0/147 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% | Total | 0/48 (0%) 1/144 (0.69%) | 0/48 (0%) Mean 0.69% | 1/48 (2%) SD 1.2% |
| *Thymus: Thymoma Malignant | | | | | | | | |
| Overall Incidence | Total | 0/49 (0%) 0/147 (0%) | 0/50 (0%) Mean 0% | 0/48 (0%) SD 0% | Total | 0/48 (0%) 1/144 (0.69%) | 1/48 (2%) Mean 0.69% | 0/48 (0%) SD 1.2% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 134

Report Date:04/29/2009

Length of Study: CHRONIC

| | | | Male | Female |
|---|--------|----------------------------|--|---|
| *Thymus: Thymoma NOS | | 0/49 (0%) | 0/50 (0%) 0/48 (0%) | 0/48 (0%) 0/48 (0%) 0/48 (0%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% SD 0% | Total 0/144 (0%) Mean 0% SD 0% |
| *Thymus: Thymoma: Benign, Malignan | t, NOS | 0/49 (0%) | 0/50 (0%) 0/48 (0%) | 0/48 (0%) 1/48 (2%) 1/48 (2%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% SD 0% | Total 2/144 (1.39%) Mean 1.39% SD 1.2% |
| *Thyroid Gland: C-Cell: Adenoma | | 0/50 (400/) | 44/50 (000) 4/50 (00) | F/F0 (400)) |
| Overall Incidence | Total | 6/50 (12%) 18/150 (12%) | 11/50 (22%) 1/50 (2%) Mean 12% SD 10% | 5/50 (10%) 6/50 (12%) 11/50 (22%) Total 22/150 (14.67%) Mean 14.67% SD 6.43% |
| *Thyroid Gland: C-Cell: Carcinoma | | 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 4/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) 0/50 (0%) Mean 0% SD 0% | 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |
| *Thyroid Gland: C-Cell: Carcinoma or Adenoma | | | | |
| Overall Incidence | Total | 6/50 (12%) 18/150 (12%) | 11/50 (22%) 1/50 (2%) Mean 12% SD 10% | 5/50 (10%) 6/50 (12%) 12/50 (24%) Total 23/150 (15.33%) Mean 15.33% SD 7.57% |
| *Thyroid Gland: Follicular Cell: Adenoma | | 0/50 (004) | 0.50 (00) | |
| Overall Incidence | Total | 0/50 (0%) 1/150 (0.67%) | 0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15% | 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|--|-------|----------------------------|-------------------------|-----------------------|-------|----------------------------|-------------------------|-----------------------|
| *Thyroid Gland: Follicular Cell: Carcinoma | | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) |
| Overall Incidence | Total | 4/150 (2.67%) | Mean 2.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | 4/50 (00() | 4/50 (00) | 2/50 (00/) | | 0/50 (0%) | 0/50 (00/) | 0/50 (40()) |
| Overall Incidence | Total | 1/50 (2%) 5/150 (3.33%) | 1/50 (2%) Mean 3.33% | 3/50 (6%) SD 2.31% | Total | 0/50 (0%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% | 2/50 (4%) SD 2.31% |
| #Tissue NOS: Lipoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Tissue NOS: Paraganglioma | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Tissue NOS: Schwannoma Malignant | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| #Tongue: Squamous Cell Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 136

| | | | Male | | | | Female | |
|--|-------------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|
| #Tongue: Squamous Cell Carcinoma | or Papillon | na Squamous | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| fTongue: Squamous Cell Papilloma | ••••• | 0/50 (00/) | 0/50 (09/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Tooth: Adamantinoma Malignant | | 0/50 (00() | 0/50 (00() | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Tooth: Odontoma | ••••• | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Jrinary Bladder: Carcinoma | | 0/50 (00() | 0/50 (00() | 0/50 /00/ | | 0/50 (00) | 0/50 /00/ | 0/50 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| Urinary Bladder: Carcinoma or Papilloma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

| Hemangiosarcoma | | | | Male | | | | Female | | |
|--|---|-------------------------------------|-------|------------|------------|------------|------------|------------|------------|------------|
| Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% "Urinary Bladder: Leiomyosarcoma 0/50 (0%) | *Urinary Bladder: Hemangiosarcoma | | | | | | | | | |
| #Utrus: Leiomyosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) | Overall Incidence | Total | ` ' | ` ' | , , | Total | ` , | ` , | ` ' | |
| Leiomyosarcoma 0/50 (0%) | | | | | | | | | | |
| Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **Urinary Bladder: Papilloma "Papilloma "Papilloma <td rowsp<="" td=""><td>*Urinary Bladder: Leiomyosarcoma</td><td></td><td>0/50 (00/)</td><td>0/50 (00/)</td><td>0/50 (00/)</td><td></td><td>0/50 (00/)</td><td>0/50 (00/)</td><td>0/50 (00/)</td></td> | <td>*Urinary Bladder: Leiomyosarcoma</td> <td></td> <td>0/50 (00/)</td> <td>0/50 (00/)</td> <td>0/50 (00/)</td> <td></td> <td>0/50 (00/)</td> <td>0/50 (00/)</td> <td>0/50 (00/)</td> | *Urinary Bladder: Leiomyosarcoma | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) |
| **Urinary Bladder: | Overall Incidence | Total | ` ' | ` ' | ` ' | Total | | | ` , | |
| Papilloma 0/50 (0%) 0/5 | | | , | | | | ` , | | | |
| Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Uterus: Adenoma Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) #Uterus: Deciduoma Benign Deciduoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) | *Urinary Bladder: Papilloma | | | | | | | | | |
| #Uterus: Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) #Uterus: Deciduoma Benign | Overall Insidence | Tatal | ` ' | ` ' | ` ' | Tatal | ` , | ` , | ` , | |
| #Uterus: Adenoma O/50 (0%) O/50 (0%) O/50 (0%) Overall Incidence Total O/150 (0%) Mean 0% SD 0% #Uterus: Carcinoma O/50 (0%) O/50 (0%) O/50 (0%) Overall Incidence Total O/150 (0%) O/50 (0%) O/50 (0%) Overall Incidence Total O/150 (0%) O/50 (0%) O/50 (0%) #Uterus: Deciduoma Benign O/50 (0%) O/50 (0%) O/50 (0%) | | | , | | | | ` , | | | |
| Overall Incidence Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% #Uterus: Carcinoma O/50 (0%) 0/50 (0%) No 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign O/50 (0%) 0/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%) | #Uterus: | | ••••• | | | | ••••• | | | |
| #Uterus: | | | | | | | 0/50 (0%) | 0/50 (0%) | ` , | |
| #Uterus: | Overall Incidence | | | | | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| Overall Incidence Total 0/150 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) | #Uterus: | | | | | | | | | |
| #Uterus: Deciduoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) | | | | | | | ` , | ` ' | ` , | |
| #Uterus: Deciduoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) | Overall Incidence | | | | | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| Deciduoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) | | | | | | ••••• | | | | |
| | #Uterus: Deciduoma Benign | | | | | | 0/50 (00/) | 0/50 (00/) | 0/50 (09/) | |
| | Overall Incidence | | | | | Total | (() () | | ` , | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Page: 138

Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: RATS

Species: RATS Strain: F344

Length of Study: CHRONIC

Vehicle: WATER

| | Male | | | Female | |
|-----------------------------|------|---|-------------------------------|---------------------------|------------------------|
| #Uterus: Hemangioma | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | 1 | Γotal | 0/150 (0%) | Mean 0% | SD 0% |
| #Uterus: Hemangiosarcoma | | | | | |
| Overall Incidence | 1 | Γotal | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Uterus: Leiomyoma | | | | | |
| Overall Incidence | ı | Γotal | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Uterus: Leiomyosarcoma | | | | | |
| Overall Incidence | 1 | Γotal | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Uterus: Polyp Stromal | | | ••••• | | ••••• |
| Overall Incidence | Т | Γotal | 7/50 (14%) 23/150 (15.33%) | 8/50 (16%) Mean 15.33% | 8/50 (16%) SD 1.15% |
| #Uterus: Sarcoma Stromal | | • | | | |
| Overall Incidence | ר | Γotal | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 139

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

| | | | Male | | | | Female | |
|-------------------------------------|-----------|-------------------------|----------------------|--------------------|-------|-------------------------------|---------------------------|------------------------|
| #Uterus: Sarcoma Stromal or Poly | p Stromal | | | | | | | |
| Overall Incidence | | | | | Total | 7/50 (14%) 23/150 (15.33%) | 8/50 (16%) Mean 15.33% | 8/50 (16%) SD 1.15% |
| #Uterus: Schwannoma Malignant | | | | | | 4/50 (00/) | 0/50 (00) | 0/50 (00/) |
| Overall Incidence | | | | | Total | 1/50 (2%) 1/150 (0.67%) | 0/50 (0%) Mean 0.67% | 0/50 (0%) SD 1.15% |
| #Vagina: Polyp | ••••• | | | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Vagina: Sarcoma | | | | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Zymbal's Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| #Zymbal's Gland: Carcinoma | | | | | | 0/50 (00) | (00) | 2/22 (22) |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 140

| | Male | | | | | Female | | | | |
|--|-------|-------------------------|----------------------|--------------------|-------|-------------------------|----------------------|--------------------|--|--|
| #Zymbal's Gland: Carcinoma or Adenoma | | 0/50 (00/) | 0/50 (00/) | 0/50 /00/\ | | 0/50 (00/) | 0/50 (00/) | 0/50 (00/) | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied